

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

HIGH STRENGTH AND HIGH DENSITY INTRALUMINAL WIRE STENT1 FIELD OF THE INVENTION:

The present invention relates generally to implantable intraluminal stents and more particularly, the present invention relates to an improved high strength intraluminal stent having increased wire density.

5 BACKGROUND OF THE INVENTION:

It is well known to employ endoprostheses for the treatment of diseases of various body vessels. Intraluminal devices of this type are commonly referred to as stents. These devices are typically intraluminally implanted by use of a catheter into various body organs such as the vascular system, the bile tract and the urogenital tract. Many of the stents are radially compressible and expandable so that they may be easily inserted through the lumen in a collapsed or unexpanded state. Some stent designs are generally flexible so they can be easily maneuvered through the various body vessels for deployment. Once in position, the stent may be deployed by allowing the stent to expand to its uncompressed state or by expanding the stent by use of a catheter balloon.

20 As stents are normally employed to hold open an otherwise blocked, constricted or occluded lumen; a stent must exhibit a relatively high degree of radial or hoop strength in its expanded state. The need for such high strength stents is especially seen in stents used in the urogenital or bile tracts where disease or growth adjacent the lumen may exert an external compressive force thereon which would tend to close the lumen.

25 One particular form of stent currently being used is a wire stent. Stents of this type are formed by single or multiple strands of wire which may be formed into a shape such as a mesh coil, helix or the like which is flexible and readily expandable. The spaces between the coiled wire permit such flexibility and expansion. However, in certain

1 situations, such as when the stent is employed in the  
urogenital or bile tract, it is also desirable to inhibit  
tissue ingrowth through the stent. Such ingrowth through  
the stent could have a tendency to reclose or occlude the  
5 open lumen. The open spaces between the wires forming the  
stent, while facilitating flexibility and expansion, have a  
tendency to allow such undesirable tissue ingrowth.

Attempts have been made to provide a stent which  
has less open space and more solid wire. U.S. Patent No.  
10 5,133,732 shows a wire stent where the wire forming the  
stent is overlapped during formation to provide less open  
space. However such overlapping wire increases the diameter  
15 of the stent and has a tendency to reduce flexibility and  
make implantation more difficult. It is therefore desirable  
to provide a wire stent which exhibits high compressive  
strength and full flexibility without allowing extensive  
ingrowth therethrough.

SUMMARY OF THE INVENTION:

20 It is an object of the present invention to  
provide an intraluminal stent which exhibits high  
compressive strength and is resistive to tissue ingrowth.

25 It is a further object of the present invention to  
provide a flexible wire stent having high compressive  
strength and maximum wire density to inhibit tissue  
ingrowth.

30 In the efficient attainment of these and other  
objects, the present invention provides an intraluminal  
stent including a generally elongate tubular body formed of  
a wound wire. The wire forming the stent is formed into  
successively shaped waves, the waves being helically wound  
along the length of the tube. The longitudinal spacing  
between the helical windings of the tube is formed to be  
less than twice the amplitude of the waves thereby resulting  
35 in a dense wire configuration.

1 As more particularly shown by way of the preferred embodiment herein, an intraluminal wire stent includes longitudinally adjacent waves being nested along the length of the tubular body. The peaks or apices of the  
5 longitudinally nested waves are linearly aligned. Further, the intraluminal stent so constructed would have a percentage of open surface area in relationship to the total surface area of the stent which is less than 30% in the closed state, resulting in less open area upon expansion  
10 which would inhibit tissue ingrowth.

**BRIEF DESCRIPTION OF THE DRAWINGS:**

Figure 1 is a perspective view of a conventional helical coil formed of a single wound wire.

15 Figure 2 is a perspective view of the stent of the present invention.

Figure 3 is a perspective view of the stent of Figure 1 exhibiting longitudinal flexibility.

20 Figure 4 is a schematic showing of one wave of the wire forming the stent of Figure 2.

Figure 5 is a schematic showing of nested longitudinally adjacent waves of the stent of Figure 2.

Figure 6 is a perspective view of the stent of Figure 2 shown in the open or exposed condition.

25 Figure 7 shows a portion of a further embodiment of a wire used to form a stent in accordance with the present invention.

Figure 8 shows a still further embodiment of a wire used to form a stent of the present invention, 30 partially wound around a forming mandrel.

**DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS:**

A simple helically formed coil spring 10 is shown in Figure 1. Coil spring 10 is formed of a single metallic wire 12 which for stent purposes may be formed of a suitably flexible biocompatible metal. The wire coil spring 10 defines generally a cylindrical tubular shape which is  
35

1 radially expandable upon application of outward radial pressure from the interior thereof.

5 The present invention shown in Figure 2, improves upon the simple coil spring 10 shown in Figure 1. However with reference to Figure 1, certain terminology used hereinthroughout may be defined. As mentioned, the spring defines a generally elongate cylindrically tubular shape lying along a central axis  $\chi$ . Wire 12 is helically wound, for example against a constant diameter mandrel (not shown),  
10 to form a longitudinally extending structure consisting of wire 12 and spaces or pitch 16 therebetween. Each individual winding 14 may be defined as the wire segment traversing one complete revolution around axis  $\chi$ . As the wire is helically coiled about axis  $\chi$ , each winding is  
15 successively longitudinally spaced from the next adjacent winding by a given distance.

20 For present purposes, the axial spacing between any point on the wire coil spring 10 to the point defining the next successive winding may be thought of as the pitch 16 of the wire coil spring 10. As so defined, the pitch of the coil spring 10 defines the spacing between windings and therefore the degree of compactness or compression of the wire coil spring 10.

25 Also with reference to Figure 1, as the wire coil spring 10 has a generally cylindrical tubular shape, it defines an outside diameter  $d_1$  and an inside diameter  $d_2$ , which would typically differ by twice the diameter  $d_3$  of wire 12. Further, wire coil spring 10 generally defines an outer cylindrical surface area along its length which may be  
30 thought of as being composed of solid surface portions defined by the outward facing surface of wire 12 itself and open surface portions defined by the spaces or pitch 16 multiplied by the number of wire windings 14. The ratio of open surface space to solid surface space may be varied by  
35 varying the so-defined pitch 16 of the wire coil spring 10. A smaller pitch coil, where the windings are more compacted or compressed, would result in an outer surface area having

1 less open space than a coil formed to have greater spacing  
or pitch between the wire windings.

5 Having set forth the definitional convention used  
hereinthroughout, the present invention may be described  
with reference specifically to Figures 2-6. A wire stent 20  
of the present invention is shown in Figure 2. Wire stent 20  
is generally in the form of an elongate cylindrically  
shaped tubular member defining a central open passage 21  
therethrough. Stent 20 is formed of multiple windings 24 of  
10 a single wire 22 which in the present invention is metallic,  
preferably tantalum, as such wire exhibits sufficient spring  
elasticity for purposes which will be described in further  
detail hereinbelow.

15 While stent 20 may be formed by helically winding  
wire 22 much in a manner shown with respect to Figure 1 to  
form wire coil spring 10, the present invention contemplates  
preshaping the wire 22 itself along its length prior to  
helically coiling the wire.

20 Referring now to Figure 4, wire 22 in an elongate  
pre-helically coiled configuration may be shaped in a manner  
having a longitudinally extending wave-like pattern. Wave  
pattern 25 is defined by a plurality of continuously  
repeating wave lengths 27 therealong. It has been found  
advantageously that the waves may take the form specifically  
25 shown in Figure 4 and 5 for optimum results as a wire stent.  
However, for explanation purposes, the wave-like pattern 25  
generally functions mathematically as sinusoidal wave,  
having a given amplitude  $A$  as measured from a central axis  
y and a peak-to-peak amplitude of  $2A$ . The wave pattern 25  
30 has a uniform preselected period  $\lambda$  equal to the transverse  
extent of a single wave length. The geometry of each wave  
length 27 is shown in Figure 4.

35 The wave-like configuration imparted to wire 22  
may be accomplished in a variety of forming techniques. One  
such technique is to pass wire 22 between the teeth of  
intermeshed gears (not shown) which would place a generally  
uniform sinusoidal wave-like crimp along the length of the

1        wire. Other techniques may be used to form the specific  
shape shown in Figure 4. Wire 22 may be passed through a  
5        pair of gear-like overlapping wheels (not shown) having  
depending interdigitating pins. By arranging the size,  
position and spacing of the pins, various wave-like  
10      configurations may be achieved. The particular shape shown  
with reference to Figures 4 and 5 has been selected as each  
wave length 27 includes a pair of non-curved linear sections  
29 between curved peaks 31. As will be described with  
15      respect to Figure 5, this configuration allows the waves to  
be stacked or nested with maximum compactness when the wire  
is helically wound around a forming mandrel (Figure 8) into  
the shape shown in Figure 2.

15      Referring now to Figure 5, schematically shown is  
a portion of stent 20 of Figure 2 which has been cut once,  
parallel to the  $x$  axis and flattened after being wound in a  
helical fashion such as that described with respect to the  
wire coil spring 10 of Figure 1. Wire 22 formed in the  
20      manner shown and described with respect to Figure 4, may be  
helically wound around an appropriately shaped mandrel  
(Figure 8). The width of the mandrel is selected in  
combination with the frequency and period of the waves  
forming wire 22 so that upon helical coiling therearound the  
waves forming each winding 24 are longitudinally stacked or  
25      nested within the waves formed by the longitudinally  
adjacent winding successively spaced therefrom.

30      As can be seen with respect to Figure 5, the peaks  
31 of the waves of longitudinally adjacent windings 24 are  
each linearly aligned so that each wave is stacked or nested  
within the next adjacent wave. In optimum configuration,  
the spacing or pitch 26 between each longitudinally  
successive winding 24 is constructed to be minimal.  
However, nesting or stacking does occur where the pitch or  
spacing between longitudinally adjacent windings 24 is less  
35      than  $2A$  i.e. the peak-to-peak amplitude. As long as the  
pitch remains less than  $2A$  each longitudinally adjacent  
winding 24 will be nested within the wave formed by the

1 previously formed winding 24. By minimizing the pitch or  
spacing 26 between adjacent windings 24, the open space  
between windings may be minimized. The particular wave-like  
5 pattern imparted to wire 22 as shown in Figure 4 allows  
particularly tight stacking of longitudinally adjacent  
windings.

The particular configuration of the stent 20 shown  
in Figure 2, provides significant advantages in medical  
10 applications. The stent 20 of the present invention is  
typically implanted by means of a balloon catheter (not  
shown). The stent 20 in a closed form is held around a  
deflatable catheter balloon. The stent is then inserted  
into the lumen and located at the desired position. The  
shape of the closed stent shown in Figure 2 permits ease of  
15 insertability. As shown in Figure 3, the stent may be  
easily bent or flexed along its longitudinal extent. The  
spacing or pitch 26 of windings 24 facilitate such bending.  
This helps in the insertion and deployment of the stent  
through a lumen, as typically body lumens traverse a  
20 tortuous path through the body which must be followed by  
the stent which is being deployed therein. Once properly  
located, the balloon is inflated and the stent is radially  
expanded for deployment. The balloon is then deflated, and  
the catheter is removed leaving the expanded stent in place.

25 The windings of stent 20 in closed condition are  
tightly nested. The cylindrical surface area formed by the  
coiled wire has greater wire density, i.e. more of the  
surface area is composed of solid wire while less of the  
30 surface area is composed by open space between the wire  
windings than in previous non-nested single wire stents.  
The wire surface area in the closed condition equals the  
wire surface area in an expanded condition. By maximizing  
the closed condition wire surface area, even when the stent  
35 is expanded such as shown in Figure 6, the expanded wire  
surface area is also maximized reducing tissue ingrowth  
between the expanded windings of the stent. Contrary to a  
simple coil spring such as that shown in Figure 1, the stent

1 20 of the present invention expands without significant  
foreshortening of the st nt or rotation of the ends of the  
coil. Rather, expansion is achieved by a flattening or  
elongation of the individual waves of the stent 20. Once  
5 the stent is expanded after deployment to a shape shown in  
Figure 6, the increased wire surface area as well as the  
particular shape of the wire provides sufficient radial  
strength to resist the compressive forces of a blocked,  
constricted or impinged upon lumen.

10 Additionally, the above-described benefits of the  
stent of the present invention are achieved without the  
necessity of longitudinally overlapping adjacent wire  
windings. In many prior art stents, the stents include  
15 portions of wire windings which are longitudinally  
overlapped. This increases the wall thickness of the stent  
thereat and results in a stent which is more difficult to  
implant in the body lumen by means of a balloon catheter.  
Also, such stents create an undesirable, more turbulent  
20 fluid flow therethrough. The stent of the present invention  
maximizes wire density, maintains a high degree of  
flexibility and radial compressive strength without  
increasing the stent wall thickness beyond the single wire  
diameter.

25 **EXAMPLE:**

Mathematically, the geometric analysis of the  
preferred embodiment of the stent of the present invention  
may be described as follows with reference to Figures 4 and  
5.

30 Each wave length 27 of the wave pattern 25 forming  
stent 20 is formed to include a straight leg segment 29 with  
a bend radius at peak 31. The angle at which the helix  
coils around the center line  $x$  (Figure 1) is assumed to be  
close to  $90^\circ$ , so that the successive windings 24 are  
35 positioned to b as close to concentric as possible while  
still maintaining a helical pattern.

1 The integer number of waves  $N$  per single circumference or single winding follows the equation:

5

$$N = \frac{\pi D}{\lambda} ;$$

where  $D$  is the diameter of the closed stent and  $\lambda$  is the period of a single wave.

10 The number of helical windings  $M$  per stent is defined by the equation:

$$M = \frac{L \sin \theta}{d_3} ;$$

15 where  $L$  is the overall stent length;  $\theta$  is the angle of the straight leg segments 29 with respect the line of amplitude of the wave pattern; and  $d_3$  is the wire diameter.

20 The exterior exposed surface area of the stent is equivalent to the amount of wire packed within a fixed stent length. The total length  $L_w$  of wire employed to form the stent follows the equation:

25

$$L_w = MN \left( 4 \ell + 4 \left( r + \frac{d_3}{2} \right) \frac{\pi}{180} (90 - \theta) \right)$$

where  $r$  is the radius defining the peak curvative; and  $\ell$  is the length of the straight line segment 29 of the wire.

30 It follows that the projected solid wire area is  $L_w d_3$  and the percentage of open space coverage (% open) is given by the equation:

$$\% \text{ OPEN} = 100 \left( 1 - \frac{L_w d_3}{\pi D L} \right)$$

1           In a specific example, a st nt having the parameters listed in Table I and formed in accordanc with the present invention yields a percentage of open space (% open) equivalent to 28.959%.

5

TABLE I

L	Length of Stent	1.000 in
D	Diameter of Closed Stent	0.157 in
$d_3$	Wire Diameter	0.010 in
10	r     Radius of Curvative of Peak	0.020 in
N	Number of Waves per Winding	3
M	Number of Windings per Stent	22.47
$\ell$	Length of Straight Portion of Stent	0.097 in

15           Further, it is found that an expanded stent constructed in accordance with the example set forth above, exhibits superior resistance to pressure P acting upon the stent in a radially compressive manner (Figure 6). In the present and illustrative example, P has been has been determined, both mathematically and empirically, to be 10 20 psi.

25           It is further contemplated that the stent of the present invention may be modified in various known manners to provide for increased strength and support. For example the end of wire 22 may be looped around an adjacent wave or extended to run along the length of the stent. The wire may be welded to each winding to add structural support such as is shown in U.S. Patent No. 5,133,732. Also, each windings may be directly welded to the adjacent winding to form a 30 support spine such as shown in U.S. Patent No. 5,019,090.

35           Further, as mentioned above, wire 22 is helically wound around a mandrel to form the helical pattern shown in Figure 1. While the angle at which the helix coils around the mandrel is quite small, a certain angle must be imparted to the uniform windings to form a coil. It is further contemplated that a helix-like winding may be formed by concentrically wrapping a wav pattern around the mandrel

1 where the length of the sides of each wave are unequal. As  
shown in Figure 7 a wave pattern 125 may be formed having  
leg segments 129 of uneven length. Wave pattern 125  
includes individual wave lengths 127 having a first leg  
5 segment 129a and a second leg segment 129b. Leg segment  
129a is constructed to be shorter than leg segment 129b.  
Thus wave pattern 125 has a step-type shape so that upon  
winding around a mandrel, the windings 124 coil in a  
10 helical-like fashion therearound. This provides a  
lengthwise extent to the coil without having to impart a  
helical wrap thereto. Forming the stent length in this  
manner may tend to result in better flow characteristics  
through the stent in use.

15 Other modifications which are within the  
contemplation of the present invention may be further  
described. Figure 8 shows a wire 222 which has been  
preformed to have a wave pattern 225 which is generally  
triangular in shape. This wave pattern 225 includes  
individual wave lengths 227 having straight leg segments  
20 229a and 229b which meet at an apex 231. Wire 222 so  
formed, may be wound around a mandrel 200. As the  
individual wave lengths 227 nest in a manner above  
described, the apices 231 of the wave length 227 are  
longitudinally aligned.

25 The winding of wire 222 around mandrel 200 takes  
place in the following manner. The formed wire 222 is held  
in position while the mandrel is rotated in the direction of  
arrow A, thereby coiling the wire 222 around mandrel 200.  
The spacing or pitch 216 is created by subsequent vertical  
30 movement of the of the formed wire 222 along mandrel 200  
while rotation thereof is taking place. When the winding is  
complete, the ends 233 of the wire 222 may be "tied off" by  
looping the end 233 around the next longitudinally adjacent  
winding.

35 While in the embodiment shown above, the amplitude  
of each wave is relatively uniform, it is contemplated that  
the wire could be formed to have waves of varied amplitude.

1 For example, the wire could be formed so that at the ends of  
the wound stent the amplitude of the waves is relatively  
small while in the central portion of the stent the  
amplitude is relatively large. This provides a stent with  
5 a more flexible central section and more crush-resistant  
ends.

In certain situations the stent of the present  
10 invention may include a membrane covering (not shown) which  
would cover the entire stent. The wire surface of the stent  
would serve as a support surface for the membrane covering.  
The membrane covering would act as a further barrier to  
tissue ingrowth. Any membrane covering may be employed with  
15 the present invention such as a fabric or elastic film.  
Further, this membrane covering may be completely solid or  
may be porous. In addition, as above described, employing  
a formed wire having varied amplitude where the amplitude of  
the wire is smaller at the ends of the stent would help  
support the membrane covering as the crush-resistant ends  
20 would serve as anchors to support the membrane covering with  
little support necessary at the more flexible central  
section of the stent.

Various changes to the foregoing described and  
shown structures would not be evident to those skilled in  
the art. Accordingly, the particularly disclosed scope of  
25 the invention is set forth in the following claims.